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The economic burden of chronic obstructive pulmonary disease (COPD) in a U.S. Medicare population[☆]

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Summary

Rationale: Although the economic burden of COPD has gained attention in recent years, data on the costs of COPD among U.S. Medicare beneficiaries are lacking.

Methods: This study used administrative claims and eligibility records from a large U.S. multi-state Medicare managed care database. Study patients were 65+ years of age with paid claims during 2004. The COPD cohort comprised patients with 1+ inpatient/ER claims or 2+ outpatient claims (>30 days apart) for COPD (ICD-9-CM codes 491.xx, 492.x, 496). The comparison cohort included patients without COPD matched 3:1 to the COPD cohort on age, sex, enrollment months, and Medicare plan. Excess costs of COPD were estimated as the difference in overall health plan payments between the two cohorts during 2004. Attributable costs were calculated using medical claims with listed diagnoses of COPD or other respiratory-related conditions and pharmacy claims for respiratory medications.

Results: A total of 8370 patients were included in the COPD cohort and were matched to 25,110 comparison cohort patients. For both groups, mean (SD) age was 78 (8) years, 54% were female, and duration of eligibility was 11 (2) months. COPD patients were more likely to utilize healthcare services and had excess total healthcare costs about \$20,500 higher ($P < 0.0001$) than the comparison cohort. Comorbidities were high in the COPD cohort, accounting for 46% of the observed excess cost. The attributable cost of COPD averaged about \$6,300; other respiratory-related costs averaged about \$4,400.

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Conclusion: In this U.S. Medicare managed care population, COPD posed a substantial burden in terms of both respiratory-related and total healthcare costs. A comparison of these cost-of-illness estimates to those for elderly COPD patients in other countries would be of great interest, given the increasing age of populations in most Western countries.

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Introduction

Chronic obstructive pulmonary disease (COPD) is a slow progressive disease characterized by airflow limitation and gradual loss of lung function that is not fully reversible.¹ It is estimated that over 12.1 million U.S. adults (4.3%) were diagnosed with COPD in 2001 and 24 million overall (8.5%) have evidence of impaired lung function.² According to the World Health Organization (WHO), at present, an estimated 80 million people worldwide have moderate to severe COPD.³ The burden of COPD is increasing and this trend is expected to continue as the populations of many Western countries age.¹

The term COPD includes chronic bronchitis and emphysema.⁴ Symptoms of COPD include cough, sputum production, wheezing, and dyspnea, with the latter being the most prominent and disabling symptom and the most common reason patients seek medical care.⁵ Diagnosis is usually made on the basis of medical history, physical examination, and results from pulmonary function testing.⁴ Treatment options for COPD are largely aimed at symptom control and reducing acute exacerbations; these include inhaled and oral bronchodilators, anti-inflammatory drugs, and supplemental oxygen.⁴

COPD also poses a substantial economic burden. Several published studies have evaluated the mean per-patient cost of COPD from the perspective of national health authorities or specific payers. Cost estimates are available from the Confronting COPD Survey for seven major countries.⁶ For the U.S., COPD cost information is available for Medicaid and commercial managed care, while other analyses have included all payers, using data from national surveys.^{7–14} However, to the best of our knowledge, only one published study focused on the cost of COPD among Medicare beneficiaries.⁸ That study used data that are more than a decade old, suggesting the need for analyses that reflect current medical practice.

The objective of the current study was to estimate the excess costs of COPD for patients enrolled in U.S. Medicare managed care plans and to place these findings in the context of international data. In the U.S., over 43 million persons are enrolled in Medicare, which primarily covers the aged (65 years and older) population, and which enacted a new program in 2006 to cover outpatient prescription medications.¹⁵ Medicare spending accounts for over 20% of all U.S. national healthcare expenditures.¹⁶

Methods

Data source

The PharMetrics Patient-Centric Database was used for this cross-sectional study. This database contains complete

healthcare information for approximately 55 million enrollees from 75 managed care organizations across each of the U.S. census regions (i.e., Northeast, South, Midwest, West). In addition, this database contains claims records for several million Medicare managed care enrollees and captures drug utilization covered under the health plans. A standard extract from the PharMetrics database was provided to us for analysis that included claims details along with eligibility data.

The claims file contained a number of specific elements for medical and pharmacy claims. Medical claims captured details regarding dates of service, place of service (e.g., hospital inpatient), physician specialty, up to 4 ICD-9-CM codes, procedure codes (in CPT-4, HCPCS level II, or revenue code format), charges, and health plan payments. Pharmacy claims included details on dispense date, National Drug Codes (NDC), quantity of medication dispensed, days' supply, and health plan payments. The eligibility file contained details on monthly medical and pharmacy eligibility, age, sex, and geographical region for individuals who were present in the claims file.

To ensure completeness of the data, records from Medicare risk plans that had known carve-outs for Medicare services (e.g., capitated skilled nursing facility and home healthcare coverage) were excluded from the final analytic database.

Patients

All patients were required to be at least 65 years of age as of January 1, 2004. Medicare beneficiaries were assigned to one of two study cohorts, as follows:

COPD cohort

Patients were eligible for the COPD cohort if they: (1) had 1 or more inpatient or emergency room claims, or 2 or more outpatient claims (separated in time by at least 30 days), with any listed diagnosis of COPD (ICD-9-CM codes 491.xx, 492.x, or 496) during 2004; and (2) were eligible for medical and pharmacy benefits in the Medicare risk plan during the month(s) of their COPD claim(s).

Comparison cohort

Patients were candidates for inclusion in the comparison cohort if they: (1) had no claims with a listed diagnosis of COPD in 2004, but had 1 or more medical claims with a valid ICD-9-CM diagnosis code for any other condition; and (2) were eligible for medical and pharmacy benefits in the Medicare risk plan during the month of their non-COPD claim.

Each COPD patient was matched to 3 patients from the comparison cohort based on age (within ± 2 years), sex, months of enrollment during 2004 (within ± 2 months), and the specific Medicare risk plan. One patient was

randomly selected from the comparison cohort pool if more than 3 eligible matches were available for that COPD case.

Study measures

Excess healthcare utilization and cost

We evaluated the use of healthcare services and medications among the COPD and comparison cohorts without regard to diagnosis (i.e., as “all-cause”). Expenditures by

the health plan (our measure of costs from the insurer perspective) were analyzed similarly. Excess costs were estimated as the paired difference in cost (i.e., between the COPD and matched comparison cohorts).

Attributable healthcare utilization and cost

Attributable healthcare resource use and costs were analyzed for the COPD cohort based on specified diagnoses and prescription drugs. COPD-related medical services were

Table 1 Characteristics and comorbid conditions for COPD and matched comparison cohorts

Measure	COPD cohort <i>n</i> = 8370	Comparison cohort <i>n</i> = 25,110	<i>P</i> -value
Age ^a :			
65–74 years (%)	34.6	34.6	N/A
75–84 years (%)	48.6	48.9	N/A
85+ years (%)	16.9	16.5	N/A
Mean ± SD	78.1 (7.5)	78.1 (7.5)	N/A
Median	77.0	77.0	N/A
Gender ^a (%):			
Male (%)	45.7	45.7	N/A
Female (%)	54.3	54.3	N/A
Region (%):			
East	28.9	28.9	N/A
South	29.1	29.1	N/A
Midwest	20.7	20.7	N/A
West	21.3	21.3	N/A
Number of months of eligibility ^a :			
Mean ± SD	11.2 (2.1)	11.2 (2.1)	N/A
Median	12.0	12.0	N/A
Selected respiratory conditions (%):			
Cystic fibrosis	0.0	0.0	N/A
Tuberculosis	0.0	0.0	N/A
Lung cancer	6.5	0.6	<0.0001
Concomitant asthma (%):	20.7	2.1	<0.0001
Charlson comorbidities (%):			
Myocardial infarction	9.5	2.9	<0.0001
Congestive heart failure	34.6	7.6	<0.0001
Peripheral vascular disease	11.1	4.0	<0.0001
Cerebrovascular disease	19.7	9.9	<0.0001
Dementia	3.8	2.2	<0.0001
Rheumatologic disease	3.5	2.1	<0.0001
Peptic ulcer disease	3.0	1.1	<0.0001
Mild liver disease	0.8	0.4	<0.0001
Diabetes without chronic complications	24.2	19.9	<0.0001
Diabetes with chronic complications	2.5	1.7	<0.0001
Hemiplegia or paraplegia	0.4	0.2	0.0008
Renal disease	9.3	3.7	<0.0001
Any malignancy	22.0	12.7	<0.0001
Moderate or severe liver disease	0.3	0.2	0.0112
Metastatic solid tumor	5.0	1.8	<0.0001
AIDS	0.1	0.0	0.0850

Source: PharMetrics database 2004.

^a Patient characteristics employed in the matching process.

required to have ICD-9-CM codes 491.xx, 492.x, or 496 listed as a primary diagnosis on an inpatient claim, or as a primary or secondary diagnosis on an outpatient claim. We considered the following types of drugs to be attributable to COPD: antibiotics and oral steroids given within 7 days of a COPD medical claim; short-acting beta-agonists; maintenance medications, including anticholinergics, inhaled steroids, long-acting beta-agonists, inhaled combination therapies, xanthines; and leukotriene antagonists. The attributable cost of COPD was calculated as the sum of all amounts paid by the health plan for medical services and drugs listed above.

For completeness, we also reported other respiratory-related medical services among patients with COPD based on having ICD-9-CM codes 460–490, 493.x–495.x, or 500–519.x listed as a primary diagnosis on an inpatient

claim, or as a primary or secondary diagnosis on an outpatient claim (as long as COPD was not listed on the same claim).

Data analyses

Descriptive analyses of patient characteristics were performed for the COPD and comparison cohorts, including demographics, number of months of eligibility, and comorbidities. Medical claims were reviewed to assess the prevalence of comorbidities. A total of 17 binary variables were created, each corresponding to a chronic disease contained in the comorbidity scale developed by Charlson and colleagues.¹⁷ The method of Deyo et al., which established ICD-9-CM codes for each of these 17 conditions,¹⁸

Table 2 Healthcare utilization for COPD and comparison cohorts, by component

Measure	COPD cohort (n = 8370)	Comparison cohort (n = 25,110)	P-value
Inpatient			
Overall hospitalizations			
Percent with one or more overall hospitalizations	55.7	14.3	<0.0001
Mean (±SD) number of overall hospital stays	1.1 (1.6)	0.2 (0.7)	<0.0001
Mean (±SD) number of overall hospital days	8.9 (17.6)	1.5 (6.5)	<0.0001
Skilled nursing facilities (SNFs)			
Percent with one or more SNF stays	9.6	2.1	<0.0001
Mean (±SD) number of SNF stays	0.1 (0.5)	0.0 (0.2)	<0.0001
Mean (±SD) number of SNF days	1.6 (8.3)	0.4 (4.0)	<0.0001
Outpatient			
Hospital outpatient (HO) services			
Percent with one or more HO services	58.4	41.3	<0.0001
Mean (±SD) number of HO services	3.7 (8.4)	1.9 (6.4)	<0.0001
Home healthcare (HHC) services			
Percent with one or more HHC services	43.4	13.2	<0.0001
Mean (±SD) number of HHC services	3.8 (8.5)	0.6 (4.0)	<0.0001
Laboratory tests and procedures			
Percent using laboratory tests and procedures	63.0	58.4	<0.0001
Mean (±SD) number of laboratory tests and procedures	1.5 (2.9)	1.1 (2.2)	<0.0001
Durable medical equipment (DME)			
Percent with one or more DME services	12.9	2.1	<0.0001
Mean (±SD) number of DME services	1.2 (4.5)	0.1 (0.8)	<0.0001
Emergency room (ER) visits			
Percent with one or more ER visits	41.1	17.6	<0.0001
Mean (±SD) number of ER visits	0.5 (1.1)	0.2 (0.6)	<0.0001
Physician visits			
Pulmonologist			
Percent with one or more pulmonologist visits	47.4	4.0	<0.0001
Mean (±SD) number of pulmonologist visits	3.9 (7.6)	0.2 (1.4)	<0.0001
Primary care			
Percent with one or more primary care visits	37.7	28.4	<0.0001
Mean (±SD) number of primary care visits	4.2 (9.1)	2.4 (6.3)	<0.0001
Overall physician visits			
Percent with one or more physician visits	91.7	85.0	<0.0001
Mean (±SD) number of physician visits	9.2 (9.0)	5.5 (6.7)	<0.0001

Source: PharMetrics database 2004.

was used to create the binary comorbidity variables from the claims database. Finally, these conditions were weighted to create a single comorbidity score.¹⁷ Chronic pulmonary disease was excluded from calculations of the comorbidity score as COPD was the disease of interest for this study.

Healthcare resource utilization and costs were reported descriptively by component for both cohorts, with excess costs calculated as the paired difference in costs between COPD patients and the matched comparison cohort. For the latter group, we used an average of the values for the 3 comparison group patients who were matched to each COPD patients. *P*-values were calculated for resource use

measures based on chi-square and Student *t*-tests. Log transformations of the paired difference (COPD vs. comparison cohort) in costs were not performed since the data curve appeared fairly bell-shaped upon visual inspection.

Multivariate analyses (least-squares means) were performed to determine excess healthcare costs while adjusting for potential differences in months of eligibility, presence of concomitant asthma, and Charlson comorbidity scores. Attributable costs of COPD and other respiratory-related healthcare utilization and costs were evaluated descriptively by component for COPD patients. All data analyses were conducted using the Statistical Analysis (SAS) software package, version 9 (SAS Institute, Cary, NC).

Table 3 Pharmacy utilization for COPD and matched comparison cohorts, by drug type

Measure	COPD cohort (<i>n</i> = 8370)	Comparison cohort (<i>n</i> = 25,110)	<i>P</i> -value
Pharmacy			
Acute medications (within 7 days of COPD claim)			
Oral corticosteroids			
Percent with one or more medications dispensed	18.0	0.0	N/A
Mean (\pm SD) number of medications dispensed	0.4 (1.1)	0.0 (0.0)	N/A
Antibiotics			
Percent with one or more medications dispensed	25.2	0.0	N/A
Mean (\pm SD) number of medications dispensed	0.4 (0.9)	0.0 (0.0)	N/A
Rescue medications			
Short-acting beta-agonists ^a			
Percent with one or more medications dispensed	35.4	2.6	<0.0001
Mean (\pm SD) number of medications dispensed	1.8 (4.1)	0.1 (0.5)	<0.0001
Maintenance medications			
Anticholinergics			
Percent with one or more medications dispensed	10.7	0.2	<0.0001
Mean (\pm SD) number of medications dispensed	0.5 (1.8)	0.0 (0.1)	<0.0001
Inhaled corticosteroids			
Percent with one or more medications dispensed	7.2	0.4	<0.0001
Mean (\pm SD) number of medications dispensed	0.2 (1.1)	0.0 (0.2)	<0.0001
Long-acting beta-agonists			
Percent with one or more medications dispensed	3.4	0.1	<0.0001
Mean (\pm SD) number of medications dispensed	0.1 (0.9)	0.0 (0.2)	<0.0001
Respiratory inhalant combinations			
Percent with one or more medications dispensed	15.7	0.7	<0.0001
Mean (\pm SD) number of medications dispensed	0.6 (2.0)	0.0 (0.3)	<0.0001
Xanthines			
Percent with one or more medications dispensed	4.5	0.1	<0.0001
Mean (\pm SD) number of medications dispensed	0.3 (1.6)	0.0 (0.3)	<0.0001
Any maintenance medication			
Percent with one or more medications dispensed	29.1	1.3	<0.0001
Mean (\pm SD) number of medications dispensed	1.7 (4.1)	0.0 (0.6)	<0.0001
Leucotriene antagonists			
Percent with one or more medications dispensed	4.0	0.4	<0.0001
Mean (\pm SD) number of medications dispensed	0.2 (1.1)	0.0 (0.3)	<0.0001
Other medications			
Percent with other medications dispensed	77.5	70.7	<0.0001
Mean (\pm SD) number of other medications dispensed	24.1 (27.6)	16.9 (21.7)	<0.0001

Source: PharMetrics database 2004.

^a Includes inhaled and oral formulations.

Results

Patient characteristics

A total of 8,370 patients met the selection criteria for the COPD cohort (Table 1) with 25,110 included in the matched comparison cohort. The mean (\pm SD) age was 78.1 (\pm 7.5) years and 54% were female. COPD patients had a significantly higher prevalence of several comorbidities, including congestive heart failure, vascular disease, diabetes, renal disease, and cancer. Approximately 20% of these patients also had a diagnosis of concomitant asthma (Table 1). Mean (\pm SD) comorbidity scores were 2.1 (\pm 2.8) and 1.0 (\pm 1.6) in the COPD and comparison cohorts, respectively.

Excess healthcare utilization and cost

The proportion of patients who were hospitalized, visited an emergency room, or utilized home healthcare services or durable medical equipment was significantly higher in the COPD cohort than the comparison cohort (Table 2). Approximately 56% of patients in the COPD cohort were hospitalized vs. 14% of those in the comparison cohort. In addition, approximately 18% and 25% of patients with COPD used oral steroids and antibiotics within 7 days of a COPD claim, respectively. Patients with COPD also were significantly more likely to be prescribed medications, especially short-acting beta-agonists (35.4 vs. 2.6%), anticholinergics (10.7 vs. 0.2%), and respiratory inhalant combinations (15.7 vs. 0.7%) (Table 3). It is noteworthy, however, that only 29% of COPD patients received a respiratory maintenance medication during 2004.

Mean total healthcare costs were approximately \$20,500 higher in the COPD cohort vs. the comparison cohort (Table 4); about 80% of this difference is accounted

Table 5 Adjusted results for excess costs controlling for eligibility, concomitant asthma, and comorbidity

Variable ^a	Parameter estimate (U.S. dollars)	t-value	P-value
Intercept	11,125 (588)	18.94	<0.0001
Months eligible	2623 (1302)	2.01	0.0440
Asthma	3153 (1200)	2.63	0.0086
Comorbidity	7824 (194)	40.34	<0.0001

^a Dependent variable was paired difference in cost (COPD minus comparison cohort).

for by excess expenditures on inpatient services. After adjusting for the burden of concomitant asthma and other comorbidities (using the Charlson score), as well as the duration of eligibility, costs were estimated to be \$11,125 higher for the COPD cohort vs. the comparison cohort (Table 5). Comorbidities accounted for approximately 46% of the excess cost.

Attributable healthcare utilization and cost

During 2004, COPD patients had substantial use of services for either COPD or other respiratory conditions. For example, approximately 47% of COPD patients had hospitalizations, 26% had emergency room visits, and 27% used home healthcare services (Table 6). Almost 60% of COPD patients visited a pulmonologist. The attributable costs of COPD averaged approximately \$6,300, while other respiratory-related costs averaged \$4,400.

Discussion

This retrospective database analysis sought to document the difference in healthcare utilization and expenditures

Table 4 Healthcare costs (mean \pm SD) for COPD and matched comparison cohorts, by component

Measure	COPD cohort, n = 8370 (U.S. dollars)	Comparison cohort, n = 8370 (U.S. dollars)
Inpatient		
Hospitalizations	19,270 (44,851)	3436 (9174)
SNF	720 (3810)	144 (933)
Subtotal	19,991 (45,773)	3580 (9393)
Outpatient		
Hospital outpatient	1661 (6349)	770 (2013)
Home healthcare services	590 (1660)	77 (337)
Durable medical equipment	89 (492)	8 (111)
Laboratory tests and procedures	159 (357)	115 (187)
Subtotal	2498 (6682)	969 (2091)
Emergency room	502 (1243)	167 (425)
Physician	867 (2485)	472 (816)
Pharmacy	1602 (4716)	860 (1919)
Other healthcare cost ^a	2197 (6792)	1077 (2653)
Total healthcare cost	27,656 (49,199)	7126 (11,242)

Source: PharMetrics database 2004.

Note: Sample size for comparison cohort based on mean of 3 controls.

^a Includes other office visits (e.g., nurse practitioners, physician assistants) and transportation services (e.g., ambulance).

Table 6 Attributable healthcare utilization for COPD patients

Measure	COPD ^a	Other respiratory conditions ^b
Inpatient		
Hospitalizations		
Percent with one or more hospitalizations	27.3	19.6
Mean (\pm SD) number of hospital stays	0.4 (0.8)	0.3 (0.7)
Mean (\pm SD) number of hospital days	3.0 (9.0)	1.7 (6.7)
Skilled nursing facilities (SNFs)		
Percent with one ore more SNF stays	0.9	0.5
Mean (\pm SD) number of SNF stays	0.0 (0.1)	0.0 (0.1)
Mean (\pm SD) number of SNF days	0.1 (2.3)	0.1 (1.3)
Emergency room (ER) visits		
Percent with one or more ER visits	16.3	10.0
Mean (\pm SD) number of ER visits	0.9 (4.2)	0.5 (3.0)
Outpatient		
Hospital outpatient (HO) services		
Percent with one or more HO services	20.8	14.4
Mean (\pm SD) number of HO services	1.3 (4.7)	0.6 (2.9)
Home healthcare (HHC) services		
Percent with one or more HHC services	22.0	4.8
Mean (\pm SD) number of HHC services	3.7 (9.6)	0.5 (3.6)
Laboratory tests and procedures		
Percent using laboratory tests and procedures	11.3	6.2
Mean (\pm SD) number of laboratory tests and procedures	0.4 (1.9)	0.2 (1.4)
Durable medical equipment (DME)		
Percent with one or more DME services	8.1	1.5
Mean (\pm SD) number of DME services	1.4 (6.4)	0.2 (1.7)
Physician visits		
Pulmonologist		
Percent with one or more pulmonologist visits	36.3	22.6
Mean (\pm SD) number of pulmonologist visits	3.8 (9.2)	1.9 (6.9)
Primary care		
Percent with one or more primary care visits	21.3	13.7
Mean (\pm SD) number of primary care visits	1.8 (6.1)	0.7 (3.1)
Overall physician visits		
Percent with one or more physician visits	61.7	37.0
Mean (\pm SD) number of physician visits	2.6 (5.1)	1.3 (8.7)

Source: PharMetrics database 2004.

^a Defined as having a primary ICD-9-CM diagnosis code of 491.xx, 492.x, or 496.^b Defined as having a primary ICD-9-CM diagnosis code of 460–490, 493.x–495.x, or 500–519.x.

between patients with and without COPD enrolled in U.S. Medicare managed care plans. We found that the per-patient cost of COPD ranged from \$6,300 using an attributable (COPD-related) cost approach to \$20,500 using an excess cost approach. When excess costs were adjusted for comorbidities and other factors, average per-patient costs were \$11,125 higher among COPD patients. A substantial portion of the costs of COPD is accounted for by inpatient stays.

From the standpoint of Medicare managed care, the excess costs of COPD are substantial. A recent review of U.S. cost studies found that those conducted since 2000 showed a range of excess costs from about \$6,100 to \$6,600, and attributable costs from \$2,700 to \$5,900.¹⁹ Our estimates of both excess and attributable costs are somewhat higher than the recent literature. One might

expect higher costs among Medicare beneficiaries vs. younger patients enrolled in managed care plans or the general population of COPD patients.

The Confronting COPD Survey estimated costs for seven countries and found that annual direct medical costs per patient (\$US 2002) were lowest in France (\$522) and the Netherlands (\$606) and highest for Spain (\$3,196) and the U.S. (\$4,119).⁶ Another study in Spain, which included patients identified from 286 general practices, found that direct annual costs averaged \$1,876.²⁰ Other COPD cost-of-illness studies evaluated data for patients experiencing exacerbations of disease^{21–23} and, therefore, are not directly comparable to the population-based estimates cited above. Published worldwide literature on the costs of COPD, despite varying methodologies, suggests that the

per-patient direct costs in many countries are substantial. COPD costs appear to be highest in the U.S. and particularly so among the elderly, as shown in this study. Additional estimates of the cost of this disease among elderly populations in other countries would be of great interest, given current demographic trends.

This study is strengthened by the use of two alternative cost estimation methods. The attributable cost approach included only medical services that had a coded diagnosis of COPD. Since most COPD patients have multiple comorbidities, in some cases those conditions may be recorded rather than COPD, which can result in an underestimation of costs attributable to COPD. This phenomenon may be especially problematic in the area of physician services, as many claims databases record only one diagnosis.

The excess cost method measures the overall difference in expenditures, regardless of diagnosis, for a cohort of patients with COPD and a comparison group of non-COPD patients matched on sociodemographic factors. For example, we found a higher prevalence of other smoking-related illnesses (e.g., cardiovascular disease, stroke, and cancer) in the COPD cohort. Comorbidity burden, as reflected in the Charlson score, was estimated to account for 46% of the observed difference in unadjusted excess costs. Because both cost estimation approaches have merit, we elected to report both here.

Our study found that approximately 29% of COPD patients received a respiratory disease maintenance medication during 2004. This rate appears to be low relative to other published studies, although we acknowledge that there are limited population-based estimates to confirm usage of maintenance medication. A Swedish study by Jansson and colleagues²⁴ found that the average number of drugs received per patient was 1.05, which may suggest a fairly high use. In an Italian study²⁵ of recently hospitalized patients with 3.4 acute exacerbations in the prior year, pre-hospital use of long-acting beta-2 adrenoceptor antagonists was 43%, while 51% received inhaled corticosteroids, and 17% received anticholinergics. However, another Italian study,²⁶ one conducted in a general practice setting, found that almost half (48%) of subjects with COPD were not treated with any respiratory drug, including short-acting beta-2-agonists. It is not clear whether the apparent low rate of drug use in our study reflects the cross-sectional nature of the study design, mild disease severity, or the extent of coverage for respiratory drugs in the health plans. Further studies of drug treatment patterns for patients with COPD would be useful.

There are several limitations to our study. First, the database includes patients enrolled in Medicare managed care plans rather than all Medicare beneficiaries. Our findings, therefore, cannot be generalized to the overall Medicare program. Although a large proportion (approximately 85%) of Medicare beneficiaries are covered by the fee-for-service programs, enrollment in Medicare managed care plans is increasing.²⁷ Second, this analysis used health insurance claims data, and medical charts were not available to confirm COPD diagnoses. The use of ICD-9-CM codes to assess prevalent cases of COPD has not, to our knowledge, been validated against objective clinical data. Third, this work did not account for patient out-of-pocket expenses in terms of cost sharing or for services not covered

by health plans. Therefore, from a societal perspective, this study underestimates the per-patient burden of COPD. Finally, this study does not directly address the aggregate burden of COPD from a national perspective. Additional studies that evaluate the comparative national and international economic burden of COPD would be of great interest.

In summary, we found that the per-patient direct costs of COPD for U.S. Medicare beneficiaries enrolled in managed care are substantial. A comparison of these cost-of-illness estimates with elderly COPD patients in other countries would be of great interest, given the increasing age of populations in most Western countries.

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